

## CHEWABLE MINERAL SUPPLEMENT

## BACKGROUND OF THE INVENTION

## 1. Field of the Invention:

This invention relates to a mineral supplement in a chewable, edible, soft candy base. More particularly, the invention pertains to a novel form of mineral supplement which contains inorganic and organic salts of elements essential to human nutrition and health. The invention also relates to the method by which these mineral supplements may be prepared.

Most particularly, the invention relates to a novel, soft candy which contains calcium carbonate as the mineral supplement for dietary calcium.

## 2. Description of the Prior Art:

The use of mineral supplements to treat human illness is well known. A variety of illnesses are caused by specific mineral deficiencies. Mineral deficiencies have also been known to cause a variety of illnesses in humans. Several of these are discussed below.

A deficiency in calcium levels may result in convulsions, tetany, behavioral and personality disorders, mental and growth retardation, and bone deformities.

Phosphorous is essential for most metabolic processes. Symptoms of phosphate deficiency include weakness, anorexia, bone demineralization, and hypocalcemia.

Magnesium is essential for the functioning of a number of critical enzymes including enzymes involved with ATP-dependent phosphorylation, protein synthesis, and carbohydrate metabolism. Magnesium deficiency also causes apathy, depression, increased CNS stimulation, delirium, and convulsions.

Lithium has been found useful in the treatment of manic-depressive illness, as a mood stabilizer, and as an antidepressive.

Sodium in the form of salts (sodium chloride) plays the major role in control of distribution of water in the body. Salt deficiency results in a diminution in extracellular space, and induces profound changes in the circulatory system. Salt deficiency leads to symptoms such as mental depression with drowsiness, apathy, anorexia, nausea and vertigo.

Potassium is the important cationic constituent of the intracellular fluid. Potassium deficiency may result in kidney damage with vacuolization of the collection tubules. Potassium deficiency is characterized by mental changes (hallucinations, loquacity) an animated facial expression and limpness of the extremities. The muscles become soft and weak.

Iron plays an important role in oxygen and electron transport. Symptoms of iron deficiency are fatigability, weakness and lassitude. Other symptoms of anemia include pallor, dyspnea on exertion, palpitation and a feeling of exhaustion.

Zinc activates a number of enzymes concerned in protein metabolism as well as some enolases and lecithinases. There is evidence to suggest that zinc deficiency may cause dwarfism and hypogonadism.

A general discussion of the the rapeutic uses of mineral compounds may be found in A. Grollman & E. F. Grollman, *Pharmacology and Therapeutics*, 7th Ed. Lea & Febiger, Philadelphia, Pa. at pages 858-873, 876, 877, 907-915.

A large number of commercial products are available which contain mineral supplements. Most of these products are available as combination products with vita-

mins. Iron supplements are generally an exception as a number of iron supplements are available as a single mineral supplement.

Mineral supplements are available in multivitamin tablets, capsules, powders, liquids and hard chewable tablet formulations. Chewable tablets have been used to overcome the dosage form size problem which results from the necessity to use large quantities of mineral salts to treat mineral deficiencies. For example, calcium deficiencies are treated with average daily doses which range from 1 to 3 grams when calcium phosphate and calcium carbonate are the calcium source to as much as 15 grams daily when calcium gluconate is the calcium source.

Hard chewable tablets offer the ability to deliver large doses of mineral supplements, however, the resultant products have a gritty mouthfeel and a taste dominated by the often salty, or bitter taste of the mineral compound.

Chewable dosage forms containing large amounts of calcium compounds have been developed in the area of antacids. Exemplary tablets contain 500 mg. to 750 mg of calcium carbonate. Non-chewable calcium supplement tablets are also known to contain 375 mg. of calcium carbonate per tablet to 1200 mg of calcium as calcium carbonate.

Canadian Pat. No. 1,165,616 to Becker, et al. discloses a soft nougat type antacid composition. The Becker, et al. product may contain calcium carbonate up to about 20% by weight as the antacid compound. To prepare a non-chalky nougat based product, Becker, et al. requires the addition of antacid to the frappe (whipped) portion of the soft candy composition. The chalky in mouth taste is avoided by coating the antacid particles having a size up to 1.5 microns with the frappe mixture prior to forming the nougat.

While the products described above may be able to deliver mineral supplements, they suffer from a variety of consumer acceptance problems. The chewable tablets are large and generally leave a chalky and or gritty sensation in the mouth. Non-chewable tablets and capsules require multiple unit dosages, i.e., 2 to 4 tablets or capsules per administration. More potent non-chewable tablets or capsules are physically so large as to be objectionable to the consumer.

The soft chewable product of Becker, et al. overcomes the taste and mouthfeel problems of hard chewable tablets. Like the smaller dose non-chewable tablets, the Becker, et al. product would require multiple dosage administration. In addition, production of the Becker, et al. product requires mineral compounds having a particle size of less than 1.5 micrometers.

It would, therefore, be desirable to develop a pleasant tasting, soft, chewable mineral supplement capable of delivering effective amounts of mineral supplements.

## SUMMARY OF THE INVENTION

A procedure for preparing a soft, chewable mineral supplement which may contain up to 40% by weight mineral compound has been unexpectedly discovered. This has been achieved by incorporating an edible polyol and a mineral compound into a soft, nougat candy base to form a soft, chewable mineral supplement having no chalky or gritty mouthfeel.